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KATRINA T. HOLLAND
Katrina T. Holland

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Staats et al.	Group Art Unit: Not Assigned
Serial No.:	**Not Assigned**	Examiner: Not Assigned
Filed:	Herewith	Docket No.: 180-102/2 DIV

For: SUBSTANTIALLY NON-TOXIC BIOLOGICALLY ACTIVE MUCOSAL ADJUVANTS IN VERTEBRATE SUBJECTS

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PRELIMINARY AMENDMENT

Commissioner for Patents
BOX PATENT APPLICATION
Washington, D.C. 20231

Sir:

Please amend the subject divisional application as of the filing date that is granted to the subject divisional application as follows:

AMENDMENTS

IN THE SPECIFICATION:

At page 1, line 3, please add the following heading and paragraph:

--Cross Reference to Related Application

This application is a Divisional of U.S. Patent Application Serial No. 09/168,910, filed October 8, 1998, the entire contents of which are herein incorporated by reference.--

IN THE CLAIMS:

Please cancel claims 1-63.

Please add the following new claims:

64. (New) A method of eliciting an immune response against an antigen in a vertebrate subject, the method comprising:

(a) providing an antigen-adjuvant composition comprising the antigen and a cytokine adjuvant selected from the group consisting of IL-1α, IL-12, IL-15, IL-18 and combinations thereof; and

(b) administering said antigen-adjuvant composition intramucosally to the vertebrate subject in a manner such that initial contact occurs in mucosal tissue of the vertebrate subject, whereby an immune response is elicited.

65. (New) The method of claim 64, wherein the antigen-adjuvant composition further comprises IL-1α in combination with at least one other cytokine.

66. (New) The method of claim 65, wherein the IL-1α is present in the antigen-adjuvant composition in an amount ranging from about 10 to about 1000 micrograms per kilogram body weight of the vertebrate subject.

67. (New) The method of claim 66, wherein the IL-1α is present in the antigen-adjuvant composition in an amount ranging from about 50 to about 500 micrograms per kilogram body weight of the vertebrate subject.

68. (New) The method of claim 67, wherein the IL-1α is present in the antigen-adjuvant composition in an amount ranging from about 60 to about 200 micrograms per kilogram body weight of the vertebrate subject.

69. (New) The method of claim 64, wherein the antigen-adjuvant composition further comprises IL-12 in combination with at least one other cytokine.

70. (New) The method of claim 64, wherein the antigen-adjuvant composition further comprises IL-15 in combination with at least one other cytokine.

71. (New) The method of claim 64, wherein the antigen-adjuvant composition further comprises IL-18 in combination with at least one other cytokine.

72. (New) The method of claim 64, wherein said manner of administration is selected from the group consisting of intranasal administration, intravaginal administration, and intrarectal administration.

73. (New) The method of claim 64, wherein the antigen-adjuvant composition is administered once a week over a period of one to three weeks.

74. (New) The method of claim 64, wherein the antigen-adjuvant composition is administered once every two weeks over a period of two to six weeks.

75. (New) The method of claim 64, wherein the antigen-adjuvant composition is administered once during a first week, and the method further comprises the step of administering the antigen only once a week over a period of one to two weeks following the first week.

76. (New) The method of claim 64, wherein the antigen-adjuvant composition is administered once during a first biweekly period, and the method further comprises the step of administering the antigen only once every two weeks over a period of two to four weeks following the first biweekly period.

77. (New) The method of claim 64, wherein the immune response comprises a systemic immune response.

78. (New) The method of claim 64, wherein the immune response comprises a mucosal immune response.

79. (New) The method of claim 64, wherein the immune response comprises a cell-mediated immune response.

80. (New) The method of claim 64, wherein the antigen-adjuvant composition further comprises a pharmaceutically acceptable vehicle and the antigen-adjuvant composition is carried therein.

81. (New) The method of claim 80, wherein the pharmaceutically acceptable vehicle is selected from the group consisting of distilled water and phosphate-buffered saline.

82. (New) The method of claim 64, wherein the antigen-adjuvant composition is free of mineral adjuvants, preservatives or stabilizers, and wherein the antigen and adjuvant are not conjugated together.

83. (New) The method of claim 64, wherein the vertebrate subject is a mammal.

84. (New) The method of claim 80, wherein the mammal is a human.

REMARKS

The specification has been amended to include a cross-reference to the co-pending parent application, U.S. Patent Application Serial No. 09/168,910, filed October 8, 1998. Claims 1-63 as presented in the parent U.S. patent application as filed were subject to a Restriction/Election Requirement, and were prosecuted in the subject parent application after initial election of IL-1β as a cytokine adjuvant species. Thus, claims 1-63 have been canceled herein. New claims 64-84 pertain to additional species of cytokines. No new matter has been added.

Discussion of New Claims

New claims 64-84 have been added. New claims 64-84 recite a method of eliciting an immune response against an antigen in a vertebrate subject in accordance with the present invention wherein the antigen-adjuvant composition comprises the antigen and a cytokine adjuvant selected from the group consisting of IL-1α, IL-12, IL15, IL-18 and combinations thereof. Support for this amendment can be found throughout the present application as filed, including page 14, line 24; page 15, lines 3-10; in the Examples; and in claims 2-34 in the parent U.S. patent application as filed. No new matter has been added.

CONCLUSIONS

If any minor issues should remain outstanding after the Examiner has had an opportunity to study the Amendment and Remarks, it is respectfully requested that the Examiner telephone the undersigned attorney so that all such matters may be resolved and the application placed in condition for allowance without the necessity for an Official Action and/or Amendment.

Deposit Account

Although a check is being submitted, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,

JENKINS & WILSON, P.A.

Date: June 5, 2001 By: _____

Arles A. Taylor, Jr.
Registration No. 39,395

Suite 1400 University Tower
3100 Tower Boulevard
Durham, North Carolina 27707
Telephone: (919) 493-8000
Facsimile: (919) 419-0383

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Enclosures